

John M. Farrell (CA Bar No. #99649)
farrell@fr.com
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 500
Redwood City, CA 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

Jonathan E. Singer (CA Bar No. #187908)
singer@fr.com
FISH & RICHARDSON P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Juanita R. Brooks (CA Bar No. #75934)
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Attorneys for Plaintiff
GILEAD SCIENCES, INC.

Additional counsel listed on signature page

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN JOSE DIVISION)**

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO, INC. (Defendant only), MERCK
SHARP & DOHME CORP. and ISIS
PHARMACEUTICALS, INC.,

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF/NMC

**GILEAD SCIENCES, INC.'S RENEWED
MOTION FOR JUDGMENT AS A
MATTER OF LAW UNDER FED. R. CIV.
P. 50(b)**

Date: November 3, 2016

Time: 9:00 am

TABLE OF CONTENTS

PAGE

NOTICE OF MOTION.....	1
I. THE JURY’S VERDICT IN FAVOR OF MERCK ON WRITTEN DESCRIPTION IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE	1
II. THE JURY’S VERDICT IN FAVOR OF MERCK ON ENABLEMENT IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.....	7
III. THE ASSERTED CLAIMS WERE DERIVED FROM, AND PREVIOUSLY INVENTED BY, PHARMASSET	9
IV. CONCLUSION.....	10

TABLE OF AUTHORITIES**Page(s)****Cases**

<i>In re '318 Patent Infringement Litig.</i> , 583 F.3d 1317 (Fed. Cir. 2009).....	8
<i>Bd. of Educ. Ex rel. Bd. of Trustees of Fla. State Univ. v. Am. Bioscience Inc.</i> , 333 F.3d 1330 (Fed. Cir. 2003).....	9
<i>Boston Scientific Corp. v. Johnson & Johnson</i> , 647 F.3d 1353 (Fed. Cir. 2011).....	2, 3
<i>CreAgri, Inc. v. PinnacLife, Inc.</i> , 11-CV-6635, 2013 WL 6673676 (N.D. Cal. Dec. 18, 2013).....	8
<i>Creative Compounds, LLC v. Starmark Labs</i> , 651 F.3d 1303 (Fed. Cir. 2011).....	9
<i>Fresenius USA, Inc. v. Baxter Int'l, Inc.</i> , 582 F.3d 1288 (Fed. Cir. 2009).....	3
<i>Fujikawa v. Wattanasin</i> , 93 F.3d 1559 (Fed. Cir. 1996).....	2, 4, 5
<i>Liebel-Flarsheim Co. v. Medrad, Inc.</i> , 481 F.3d 1371 (Fed. Cir. 2007).....	9
<i>Novozymes A/S v. DuPont Nutrition Biosciences APS</i> , 723 F.3d 1336 (Fed. Cir. 2013)	4, 5
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed. Cir. 2008).....	1
<i>Purdue Pharma L.P. v. Faulding Inc.</i> , 230 F.3d 1320 (Fed. Cir. 2000).....	2
<i>Rasmusson v. SmithKline Beecham Corp.</i> , 413 F.3d 1318 (Fed. Cir. 2005).....	7, 8
<i>In re Ruschig</i> , 379 F.2d 990 (C.C.P.A. 1967)	2, 4, 5
<i>Tawnsaura Group, LLC v. Maximum Human Performance, LLC</i> , CV 12-07189, 2014 WL 10473254 (C.D. Cal. Jul. 14, 2014).....	7, 8
<i>Wyeth & Cordis Corp. v. Abbott Labs.</i> , 720 F.3d 1380 (Fed. Cir. 2013).....	8, 9

Statutes

35 U.S.C. § 102(f).....9

35 U.S.C. § 102(g)10

Other Authorities

Fed. R. Civ. P. 50(b)1, 3

NOTICE OF MOTION

PLEASE TAKE NOTICE THAT on November 3, 2016 at 9 A.M., or as soon thereafter as counsel may be heard by the Honorable Beth Labson Freeman, United States District Court for the Northern District of California, Robert F. Peckham Federal Building, 280 South 1st Street, San Jose, California 95113, Plaintiff Gilead Sciences, Inc. will, and hereby does, move the Court to enter judgment as a matter of law (“JMOL”) under Fed. R. Civ. P. 50(b) that the asserted claims of U.S. Patent Nos. 7,105,499 and 8,481,712 are invalid for (1) lack of written description; (2) lack of enablement; and (3) because Defendants derived the subject matter of the asserted claims from Pharmasset, whom invented prior to Defendants.¹

MEMORANDUM OF POINTS AND AUTHORITIES

I. THE JURY’S VERDICT IN FAVOR OF MERCK ON WRITTEN DESCRIPTION IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE

This case is a textbook example of lack of written description support for the claimed inventions. As such, the jury’s verdict in favor of Merck should be set aside.

Each of the asserted claims of the two patents-in-suit involves a sub-genus of one of the broader chemical genres in the patents’ shared specification. Claims 1 and 2 of the ’499 patent, and claims 9, 10 and 11 of the ’712 patent cite to Formula III in the specification, while Claims 1, 2, 3, 5, and 7 of the ’712 patent cite to Formula I. (Tr. 751:19-25, 752:13-753:7, 778:9-14 (Secrist); EX-1; EX-2.)

As conceded by Merck’s expert, none of the claimed sub-genuses is expressly described in the specification. (Tr. at 1577:4-25, 1594:1-10, 1618:2-13 (Wuest); *id.* at 751:2-753:7, 778:3-781:1, 882:3-13 (Secrist).) Claim 10 of the ’712 patent is illustrative. (EX-2.0076.) Though Claim 10 cites to Formula III in the specification, Formula III covers “billions and billions of

¹ Under Federal Circuit law, the Court’s determination that the ’499 and ’712 patents are unenforceable as to Gilead may moot Gilead’s request for JMOL. *See, e.g., Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1322 (Fed. Cir. 2008) (explaining that “[a] determination of unenforceability bars a finding of infringement, and similarly moots any issue of invalidity” (internal citations omitted)). Gilead nonetheless makes this Motion so that the Court may make that determination and so as to present alternative arguments in support of the judgment.

1 compounds,” while Claim 10 is “dramatically narrow[er] in focus,” covering only around 100 to
2 200 nucleosides. (Tr. at 748:20-749:25, 778:17-779:16, 887:15-24 (Secrist); *id.* at 1594:16-25
3 (Wuest).) Like all the asserted claims, Merck prepared Claim 10 in hindsight by narrowing
4 Formula III, based on later-learned knowledge of the structure and activity of Pharmasset’s
5 compounds, and not based on any description in the patent. (See ECF No. 422, ¶ 158; *id.* at 46.)

6 Where a chemical sub-genus is not expressly described in the specification, it lacks
7 written description unless the specification contains indicia – or “blaze marks” – to direct a
8 skilled artisan to that specific sub-genus, thus demonstrating that the inventors possessed the sub-
9 genus at the time they filed the original application. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571
10 (Fed. Cir. 1996). “In the absence of such blazemarks, simply describing a large genus of
11 compounds is not sufficient to satisfy the written description requirement as to particular species
12 or sub-genuses.” *Id.* at 1571. Thus, a chemical sub-genus will not have written description
13 support “just because a [chemical] moiety is listed as one possible choice for one position [on the
14 generic compound’s structure].” *Id.* at 1571. “[S]uch a disclosure would not ‘reasonably lead’
15 those skilled in the art to any particular species.” *Id.* “[S]omething more than the disclosure of a
16 class of 1000, or 100, or even 48, compounds is required....[O]ne cannot disclose a forest in the
17 original application, and then later pick a tree out of the forest and say here is my invention.”
18 *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326-27 (Fed. Cir. 2000).

19 Satisfying the “blaze marks” requirement necessitates “the disclosure of either a
20 representative number of species falling within the scope of the genus or structural features
21 common to the members of the genus so that one of skill in the art can visualize or recognize the
22 members of the genus.” *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1363
23 (Fed. Cir. 2011) (internal quotation marks omitted) (affirming judgment of no written description
24 for chemical sub-genus). “In order to satisfy the written description requirement, the blaze
25 marks directing the skilled artisan to [the claimed sub-genus] must be in the originally filed
26 disclosure.” *Purdue Pharma*, 230 F.3d at 1326-27; *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A.
27 1967) (finding no evidence of possession of the claimed invention where specification neither
28

1 named claimed compound nor included a “guide indicating or directing that this particular
2 selection should be made rather than any of the many others which could also be made”).

3 At trial, the jury did not hear any evidence, much less “substantial evidence,”² that might
4 sustain its written description verdict under these standards. It was stipulated that no compound
5 described by structure in the examples of the specification is recited within the asserted claims.
6 (ECF No. 300, ¶ 1; *see also* ECF No. 422, ¶¶ 164-68.) The experts also agreed that the
7 specification does not contain even one example of, or otherwise depict, name, or mention, even
8 one compound, or “species,” that falls within the claimed sub-genuses. (Tr. at 742:13-18,
9 753:20-755:21, 781:2-21 (Secrist); *id.* at 1572:3-6 (Wuest).) The specification’s utter failure to
10 disclose any species within the claimed sub-genuses—let alone a sufficient number of such
11 representative species—by itself strongly supports granting JMOL. *Boston Scientific*, 647 F.3d
12 at 1363-64 (lack of examples considered in evaluating written description and requiring
13 disclosure of representative species or features common to the sub-genus).

14 And while Merck’s expert, Dr. Wuest pointed to a handful of examples in the patent of
15 some compounds with a 2’-methyl up group, or with a 2’ or 3’ fluorine down, or with single-ring
16 bases, **none** of those examples were of compounds containing all three of these elements
17 **together** as required by the claims. (Tr. at 1555:1-1558:1; 1580:1-1584:20 (Wuest).) Dr. Wuest
18 also failed to point to any disclosure in the specification directing one of skill to put those
19 separately disclosed elements together to come up with any of the claimed sub-genuses that
20 encompass compounds having all three elements in combination. Instead, when questioned
21 about the lack of examples, Dr. Wuest pointed twice to boilerplate in the patents that “the
22 examples were not meant to limit the invention,” to explain away the lack of disclosure. (*Id.* at
23 1572:15-25, 1633:3-9 (Wuest).)

24 Merck’s expert’s reliance on separate disclosures of compounds with some—but not
25 all—individual claim elements are nowhere close to the required blaze marks toward the claimed

26 _____
27 ² *See Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1294 (Fed. Cir. 2009) (Rule 50(b)
28 requires showing that jury’s verdict is not supported by substantial evidence).

1 sub-genuses, and thus cannot and do not satisfy the written description requirement under the
2 cited Federal Circuit authorities. The court in *Novozymes A/S v. DuPont Nutrition Biosciences*
3 *APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) invalidated a patent for lack of written description on
4 very similar facts. In *Novozymes*, the court had to determine if the specification demonstrated
5 the patentee had invented a claimed group of “alpha-amylase variants” that, as here, the
6 inventors claimed after the fact, “almost a decade later.” *Id.* at 1348. There was no disclosure of
7 **any** variant encompassed by the claims, and while the separate elements describing the claimed
8 variants were individually listed at various places in the disclosure, they were not described
9 together as a group or combination of elements. *Id.* at 1348-49. The disclosure therefore did not
10 describe the claimed invention. *Id.* at 1349 (“Taking each claim—as we must—as an integrated
11 whole rather than as a collection of independent limitations, one searches the 2000 application in
12 vain for the disclosure of even a single species that falls within the claims or for any “blaze
13 marks” that would lead an ordinarily skilled investigator toward such a species among a slew of
14 competing possibilities.”). In addition, the disclosure “lack[ed] any indication” the inventors had
15 actually invented the claimed variants because the examples and disclosure were limited in
16 nature and, in particular, deficient with respect to the claimed variants. *Id.* The absence of
17 “blaze marks” thus compelled the conclusion that the inventors did not possess the claimed
18 invention at the filing date, and that the patent was invalid. *Id.*

19 The same result should be reached here. There is no disclosure in the specification of
20 **any** compound encompassed by the claims, as the parties and experts agreed. And although
21 there are broad formulas in the patent that contain the claimed sub-genus’ features amongst their
22 many possibilities and thus, in hindsight, the correct selections among the billions of compounds
23 can be made to artificially construct the claimed sub-genuses, that is not enough. The Federal
24 Circuit and its predecessor courts have invalidated claims to a sub-genus or compound that was
25 within a broad formula where, as here, the specification contained no blaze marks leading to the
26 claimed invention. *Fujikawa*, 93 F.3d at 1571; *In re Ruschig*, 379 F.2d at 994-96. The reason
27 for this is the simple concept that to be entitled to patent monopoly rights, the inventors must
28

1 actually possess the claimed invention and demonstrate as much by including blaze marks
2 toward *that* invention in their specification when they file their patent application.

3 Faced with the specification's deficiency, both Dr. Wuest and Merck's counsel turned the
4 jury instructions on their head, causing the jury to misapply those instructions and reach the
5 wrong conclusion. Dr. Wuest denounced the blaze mark analysis that defines the written
6 description requirement. He testified *contrary to controlling law* that the test for written
7 description is *not*, as Dr. Secrist described, determining "if there's a particular focus on this
8 particular set of compounds in this particular specification," because "that's not the test for
9 written description as it's been explained to me." (Tr. at 1579:15-23 (Wuest).) Instead, Dr.
10 Wuest wrongly opined that written description is satisfied as long as each limitation of the sub-
11 genus can be found somewhere in the specification. (*Id.* at 1577:12-25, 1591:1-16, 1593:15-
12 1594:10 (Wuest).) In his legally incorrect words, "[A]s the written description requirement has
13 been explained to me by counsel, nothing else has to be done. That is what is required. You
14 need to find the expression, the visibility of these elements in the specification, and you do that."
15 (*Id.* at 1579:1-8 (Wuest).) Merck's counsel, too, incorrectly characterized the court's
16 instructions in closing arguments. Just like its expert, Merck argued that written description is
17 satisfied simply if the limitations of the claimed sub-genus can be found, separately, somewhere
18 in the specification. (*See, e.g., id.* at 1698:15-20, 1699:7-9, 1712:3-12.)

19 Contrary to Dr. Wuest's testimony and Merck's counsel's argument, the mere ability to
20 "piece together" a claimed sub-genus from a broader disclosure, or recognize in hindsight that
21 sofosbuvir's metabolites are a few of the billions of compounds that could theoretically be
22 constructed from the broader disclosure, does not legally satisfy the written description
23 requirement. The Federal Circuit has repeatedly rejected this approach. *Novozymes*, 723 F.3d at
24 1346-49; *Fujikawa*, 93 F.3d at 1571; *In re Ruschig*, 379 F.2d at 995. (*See also* Tr. at 1618:2-21
25 (Wuest).) **Blaze marks** from the broader formulas to the claimed sub-genuses are required.

26 Merck's fact witnesses likewise failed to identify any blaze marks to the claimed
27 inventions. Merck's key fact witness on written description, Dr. Durette, who the Court found
28

lacked credibility, was the centerpiece in Merck’s argument that PSI-6130 could be found in the specification’s broad formulas if one looked for the individual features, and that the specification included examples of compounds separately having some, but not all, of claimed compounds’ features, as repeated by Dr. Wuest. (Tr. at 391:24-392:12, 394:16-395:13, 398:25-399:23 (Durette); *see* ECF No. 422, ¶¶ 141, 143, 145, 147, 162, 163, 170.) Dr. Durette also told the jury that it was “totally acceptable within the patent practice” to claim something if “it was a selection of one member of a Markush group.” (Tr. at 402:25-403:17 (Durette).) As discussed above, such reasoning is legally wrong. Likewise, the only Merck inventor to testify at trial, Dr. Olsen, merely pointed to the specification’s broad generic formulas, and failed to identify any blaze marks to the claimed inventions. (*See, e.g., id.* at 928:12-23, 1093:16-1095:1 (Olsen).)

The only reasonable conclusion supported by the evidence when the required “blaze mark” analysis is applied is that the asserted claims are invalid for lack of written description. Gilead’s expert, Dr. Secrist, was the only expert to apply the blaze mark analysis by looking for guidance in the specification to the claimed sub-genuses, though he searched in vain. (*Id.* at 738:22-739:4; 751:19-752:12, 783:19-784:7, 820:7-15 (Secrist).) He explained that there is “absolutely nothing” in the specification that would lead the skilled artisan to the claimed sub-genuses. (*Id.* at 750:1-7 (Secrist).) None of the claimed sub-genuses are expressly described in the specification, and the specification does not include any blaze marks leading from the broader, disclosed formulas to the narrower, undisclosed sub-genuses that are claimed. (*Id.* at 751:2-753:7, 778:3-781:1, 882:3-13, 885:12-19; *id.* at 1618:5-7 (Wuest).) As Dr. Secrist put it, “[T]here’s no guidance at all to get from this massive set of compounds [in Formula I] to the still very massive set in claims 1 through 3 [of the ’712 patent].” (*Id.* at 780:20-22 (Secrist).)

The lack of written description support for the asserted claims is no surprise given the underlying facts of the case. Merck never made or tested a single compound falling within the asserted claims by the asserted priority date. (ECF No. 300, ¶ 2; ECF No. 422, ¶¶ 163-66.) None of the specification’s examples are recited within the asserted claims. (ECF No. 300, ¶ 1.) And the specification contains no biological data whatsoever, let alone for any compound within

the scope of the claims. (Tr. at 782:2-783:18 (Secrist); *id.* at 1574:16-18 (Wuest).) As the Court noted in its unclear hands ruling, the claims are not the result of Merck's work, but rather Merck's claiming of Pharmasset's confidential information. (ECF No. 422 at 45-47.)

Accordingly, there is no written description support for the sub-genuses Merck ultimately claimed—no blaze marks, species or other guidance demonstrating that the inventors actually invented and possessed the claimed sub-genuses as the law requires—and no contrary conclusion can be drawn from the evidence. JMOL should be granted.

II. THE JURY'S VERDICT IN FAVOR OF MERCK ON ENABLEMENT IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE

“[W]here there is no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to demonstrate that the claimed products do have those effects,” the patentee has failed to disclose a practical utility and the patent is invalid for lack of enablement. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005) (internal punctuation omitted). Further, a “complete absence of data supporting the statements which set forth the desired results of the claimed invention” supports finding a lack of practical utility. *Id.* Situations where bare statements or reasoning demonstrate utility are “rare.” *Tawnsaura Group, LLC v. Maximum Human Performance, LLC*, CV 12-07189, 2014 WL 10473254, at *13 (C.D. Cal. Jul. 14, 2014).

As with written description, the jury did not hear substantial evidence to support its enablement verdict on the issue of practical utility. Merck's expert, Dr. Wentland, relied exclusively on unsupported statements in the specification alleging that “compounds of the invention” (not the compounds actually claimed) were useful. (*See, e.g.*, Tr. at 1315:13-1316:9, 1320:1-1321:13, 1323:3-7 (Wentland).) He could not point to anything else because it was undisputed that as of January 2002 Merck had not tested any compounds recited within the asserted claims, and that the specification contains no data at all for any of the claimed compounds. (ECF No. 300, ¶ 2; Tr. at 561:6-23 (Seeger); *id.* at 1379:12-22 (Wentland).) *See Rasmusson*, 413 F.3d at 1323 (specification must demonstrate a practical utility for the claimed

1 invention). In closing, Merck doubled down on Dr. Wentland’s argument, misapplying the
 2 Court’s enablement jury instruction and arguing that it requires nothing more than a bare
 3 assertion of utility in the specification: “The instruction tells you, if we disclose it, that’s it. ...
 4 [T]he Instructions don’t say anything about data ... it doesn’t say you have to prove anything. It
 5 says you have to disclose it, which we did.” (Tr. at 1700:23-1702:10.) This argument is wrong
 6 as a matter of law—evidence substantiating an alleged utility must be included in the
 7 specification “unless one of ordinary skill in the art would accept the allegations as obviously
 8 correct.” *Rasmusson*, 413 F.3d at 1323; *Tawnsaura*, 2014 WL 10473254, at *13; *CreAgri, Inc.*
 9 *v. Pinnaclelife, Inc.*, 11-CV-6635, 2013 WL 6673676, at *20 (N.D. Cal. Dec. 18, 2013).

10 At trial, Gilead’s experts presented substantial evidence that skilled artisans would not
 11 accept the bare statements in the specification as obviously correct without substantiating data,
 12 including unrebutted testimony that the study of nucleosides to target HCV was a new and highly
 13 unpredictable field. (*See, e.g.*, Tr. at 565:10-568:25, 579:20-581:1 (Seeger); *id.* at 791:20-802:9
 14 (Secrist).) As Dr. Secrist testified, enabling the use of Merck’s claimed inventions would
 15 amount to a research project, because there is no guidance within the specification. (*Id.* at
 16 802:22-803:20 (Secrist).) But mere research proposals cannot be patented. *In re ’318 Patent*
 17 *Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009).

18 Merck’s alternative arguments—based on sofosbuvir and compounds Merck purchased
 19 from Idenix in 2014, all of which were developed well after 2002—likewise fail to demonstrate a
 20 practical utility for the claimed inventions. (*E.g.*, Tr. at 1324:10-1325:9 (Wentland)). None of
 21 that information was available to skilled artisans as of Merck’s January 2002 filing date, when
 22 utility and enablement are assessed. *In re ’318 Patent Litig.*, 583 F.3d at 1323. The substantial
 23 evidence demonstrates that the asserted claims lack utility. JMOL should be granted.

24 Claims are also not enabled when, as of the effective filing date, skilled artisans could not
 25 practice their full scope without undue experimentation. *Wyeth & Cordis Corp. v. Abbott Labs.*,
 26 720 F.3d 1380, 1384 (Fed. Cir. 2013). Merck also failed to rebut the substantial evidence
 27 presented at trial by Gilead that skilled artisans could not use the millions of compounds of
 28

Claims 1, 2, 3, 5 and 7 of the '712 patent, and in the case of the '499 patent, all prodrugs of the claimed compounds, without undue experimentation. (Tr. at 661:17-683:5 (Stella); *id.* at 789:17-803:20 (Secrist).) Rather, Merck built its enablement case on an erroneous jury instruction. (See Tr. at 1642:15-24.) That instruction states that “the enablement requirement is met if the specification enables any mode of making and using the invention” (ECF No. 352 at 30), which is contrary to the requirement that there must be enablement of the full scope of the claimed range. *Wyeth*, 720 F.3d at 1385-86; *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379-80 (Fed. Cir. 2007). The scope of claims 1 and 2 of the '499 patent, and 1-3, 5 and 7 of the '712 patent are enormous – encompassing millions and billions of compounds – without even considering the “prodrug” aspect of claims 1 and 2 of the '499 patent. Merck’s expert, Dr. Langer, wrongly testified that the full scope of the claims do not have to be enabled, agreeing with Merck’s counsel that enabling prodrugs is unnecessary under this “any mode of making” jury instruction. (Tr. 1223:12-1224:5 (Langer).) Under the correct law, the only conclusion the jury could have reasonably reached was that these claims are not enabled. JMOL should be granted.

III. THE ASSERTED CLAIMS WERE DERIVED FROM, AND PREVIOUSLY INVENTED BY, PHARMASSET

Derivation under § 102(f) requires proof of (1) prior conception of the invention by another and (2) communication of that conception to the patentee. *Creative Compounds, LLC v. Starmark Labs*, 651 F.3d 1303, 1313 (Fed. Cir. 2011). Conception of chemical compounds requires “knowledge of **both** the specific chemical structure of the compound **and** an operative method of making it.” *Bd. of Educ. Ex rel. Bd. of Trustees of Fla. State Univ. v. Am. Bioscience Inc.*, 333 F.3d 1330, 1341-1342 (Fed. Cir. 2003) (emphases added).

Pharmasset completed conception of PSI-6130 no later than May of 2003 when Jeremy Clark knew its structure and had made it. (EX-503 at 27; Tr. at 504:8-11 (Otto).) It is undisputed that Pharmasset communicated this conception to Merck through (a) the disclosure of PSI-6130’s structure to Dr. Durette in March 2004 (EX-2098; Tr. at 433:2-4 (Roemer); ECF No.

422 at ¶¶ 77-78, 81); and (b) the publication of Clark’s patent application in January 2005 containing an operative method of making PSI-6130. (EX-155 at 31; ECF No. 422 at ¶¶ 158-159, 169.) Thus, the only remaining question is whether Merck conceived of PSI-6130 before these communications. Merck did not, and no reasonable jury could conclude otherwise based on the substantial trial evidence.

As the Court has found, and Defendants’ corporate representatives confirmed, neither Isis nor Merck ever made PSI-6130, or any 2’ methyl up, 2’ fluoro down nucleoside, until August 2005. (EX-2381 at 123:15-124:1 (Bennett); EX-2382 at 46:22-25 (Duffy); ECF No. 422 at ¶¶ 166, 168, 169.) And no Merck witness rebutted Dr. Secrist’s testimony that he had seen no evidence that Merck made—or even knew how to make—a compound with the structure of PSI-6130 until after the Clark application published. (Tr. at 880:15-881:10 (Secrist).)

With respect to prior invention, the same evidence establishes that Pharmasset, through Jeremy Clark, invented PSI-6130 before Merck did. And Mr. Clark did not “abandon[], suppress[], or conceal[]” his invention because it was published in 2005. 35 U.S.C. § 102(g).

The jury never reached these issues because both the jury instructions, to which Gilead objected (ECF No. 352 at 32-33; Tr. at 1643:1-18), and the verdict form (ECF No. 330) prevented them from doing so in view of their written description and enablement decisions which, as explained above, are not supported. JMOL should now be granted.

IV. CONCLUSION

For the reasons set forth above, Gilead respectfully requests that the Court enter JMOL that the asserted claims of the ’499 and ’712 patents are invalid.

Dated: July 5, 2016

FISH & RICHARDSON P.C.

By: /s/ Elizabeth M. Flanagan

Elizabeth M. Flanagan

Attorneys for Plaintiff

GILEAD SCIENCES, INC.

1 *Additional counsel:*

2 Douglas E. McCann (*Pro Hac Vice*)
3 dmccann@fr.com

4 Gregory R. Booker (*Pro Hac Vice*)
5 booker@fr.com

6 Robert M. Oakes (*Pro Hac Vice*)
7 oakes@fr.com

8 Elizabeth Flanagan (*Pro Hac Vice*)
9 eflanagan@fr.com

10 Joseph B. Warden (*Pro Hac Vice*)
11 warden@fr.com

12 FISH & RICHARDSON P.C.

13 222 Delaware Avenue, 17th Floor
14 Wilmington, DE 19801

15 Telephone: (302) 652-5070

16 Facsimile: (302) 652-0607
17
18
19
20
21
22
23
24
25
26
27
28

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on July 5, 2016, to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Civil Local Rule 5-1(h)(1).

/s/ Elizabeth M. Flanagan
Elizabeth M. Flanagan